Only one rejection remains in this case, the 35 USC §112, first paragraph rejection, i.e., the "written description" rejection. Applicants respectfully request reconsideration of the rejection based upon the claim amendment and the following argument.

The inventors had possession of a small sub-species of avian reoviruses, i.e. a homogeneous group of ERS isolates, which are characterized by a combination of structural- and (immunological) functional characteristics. The claimed viruses are defined by the isolates being:

1. avian reoviruses,
2. which can neutralize (in a plaque reduction assay) a specific ERS isolate that is deposited as an isolate belonging to the homogeneous group of ERS isolates, and that
3. comprises epitopes common for avian reoviruses, as evidenced by their binding with polyclonal avian reovirus antiserum, but that lack the presence of specific epitopes that bind with the specified moabs which, however, are present on the known avian reovirus isolates.

Property No. 1 represents a multitude of structural features that are routinely applied in virology. In fact, the Examiner on page 7 of the office action has listed many these features. By characterizing the claimed isolates as an avian reovirus, these isolates are inherently defined by the well-known properties of avian reoviruses. Further, these properties are, for example, listed in standard textbooks, such as: Virus Infections Of Birds, eds.: Mc Ferran and McNulty, Elsevier Science Publishers B.V., 1993, pages 177 and 181. (see Applicants previous responses).

However, these properties, while Applicants contend sufficient to define the reoviruses, have been further defined by the inventors, and, at the same time further

distinguish them from the prior art avian reovirus isolates using specific immunological properties of the novel (properties No. 2 and No. 3).

In this respect, it is important that the two following aspects are considered by the Examiner:

A. These properties are the properties used in the art to demonstrate (structural) similarity between members of a group of related viruses and to distinguish them from unrelated agents.

B. These properties provide an art-recognized correlation or relationship between function and structure.

The accuracy of these statements is extensively argued and documented in Applicants' previous submissions and reference is made to these. No evidence has been presented which suggests or discounts the veracity of the documentary proof Applicants made in support of their claims. The written description is sufficient for one skilled in the art to practice the invention.

Accordingly, in contrast to the Examiner's statement that "the claim fails to incorporate any meaningful structural or functional limitations that would readily allow the skilled artisan to identify whether or not they were in possession of the claimed subject-matter," the claimed properties do establish the structural and functional limitations, as evidenced by the publications in the art.

Further, Example 1B-C, Tables 2 A and B, show possession by the inventors of a representative number of ERS isolates isolated and characterized by the inventors. The

characterization methods being those of the Claims, thereby enabling one of ordinary skill in the art to practice the invention from the written description given.

Next, Applicants would like to respond to the Examiner's comments concerning the three references submitted with the previous response:

To begin, it is noted that these references were submitted merely as further technical evidence to rebut the Examiner's position that the properties used in the claims to define the ERS isolates do not provide a correlation between function and structure. The references just do that.

Second, it is unclear from where the Examiner's statements concerning how the references show that the ERS isolates of the present invention cannot be distinguished from the known avian reovirus isolates by means of the properties used in the claims. These references do not disclose such a specific teaching by because these references deal with other specific situations. Therefore, the conclusion reached by the Examiner is not supported by verifiable facts.

In contrast, the verifiable facts in the Examples unambiguously demonstrate that the (combination of) properties used in the Claims to define the ERS isolates are sufficient to characterize these isolates and to distinguish them from the known avian reovirus isolates (see Tables 2 A and B and Table 3).

Third, in addition, the teachings derived from the three reference are also not correct as such:

a) Estes et al.:

The fact that this reference does not describe the usefulness of plaque reduction assays in characterizing closely related rotaviruses (because rota viruses originating from different

mammalian species were investigated) does not imply that does not imply that this method is not suited for this purpose. In particular, the reference states that the plaque reduction tests will become useful in distinguishing serotypes of new isolates (last paragraph on page 152).

The fact that the reference (1980) states that the success of this test is dependent on the production of appropriate antiserum cannot be taken out of context by the Examiner in support of his opinion that the conduct of such test may require undue burden. Applicants have demonstrated (by the submission of various documents-from standard text books) that plaque reduction test are among the most common tests used by the skilled artisan without any difficulty. The specification proves that (and illustrates how) such tests can be carried out without any difficulty.

The Examiner mistakenly submits that all reovirus isolate (ERS and non-ERS) are able to induce a plaque reduction of an ERS isolate. Table 2A shows that none of the antisera obtained from the known avian reoviruses is able to cause plaque reduction of the tested ERS isolates (as required in the claim for ERS isolates). Interestingly, the Table shows that antiserum obtained from ERS isolate (no. 2) is able to cause (also) plaque reduction of non-ERS isolates. This only shows that the antigenic spectrum of the ERS isolate is broader than that of the other avian reovirus isolates (despite the fact ERS isolates lack the presence of the epitopes specified by the moabs). Consequently, this makes ERS isolates interesting vaccine candidates.

b) Green et al.

First, referring also to the Examiner's comments to Estes et al. above, this reference teaches that plaque reduction neutralization (PRN) and moab binding can be used to serotype human rotaviruses and that this correlates with structural (i.e. sequence) properties (page 1819, 1st paragraph; page 1820, Table 1 and right column, 2nd paragraph). Second, in contrast

to what the Examiner states, Green et al. does not refer to a panel of monoclonal antibodies to be used to ascertain a serotype of a particular rotavirus isolate. Green et al. refers to the identification the serotype of a rotavirus by means of a serotype-specific moab (page 1819, Abstract; 1st paragraph). This is further confirmed by the Coulson et al., 1987 document, mentioned in Green et al.: individual monoclonal antibodies can be used as reagents that evaluate the serotype of rotavirus (Abstract; page 510, Table 1).

These documents illustrate that a moab can be used to distinguish between the presence or absence of certain epitopes on virus isolates.

In the present invention, the moabs are used to characterize and distinguish the claimed isolates from the known avian reovirus isolates by the absence of certain epitopes that are present on the known reovirus isolates.

c) Kang et al.

The Examiner questions the validity of the use moabs to discriminate between viruses, merely because not all moabs display the desired property, such as moab RG36H9 mentioned by Kang et al. In rebuttal, of course, not all moabs generated against a certain virus bind with unique epitopes. Moabs are generated against epitopes that are present on all types of isolates of a certain virus, whereas other moabs have a more unique character. This property is illustrated in Table 3 of the present specification. The moabs mentioned in the claims bind with epitopes that are not present in the claimed ERS isolates, but demonstrate that the known isolates have such epitopes.

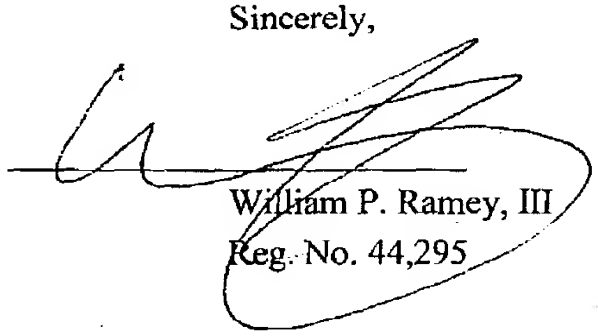
Moabs 154 and 14-67 bind with common epitopes present on both ERS isolates and the known avian reovirus isolates.

In conclusion, the three references do illustrate Applicants claimed invention as having an adequate written description.

IV. CONCLUSION

In light of the Argument above, Applicants respectfully request reconsideration of the rejection and allowance of the case. Applicants further respectfully request that a personal interview be granted prior to further action by the Examiner. Please charge any required fees to deposit account 02-2334 and credit any credits. Further, Applicants respectfully petition for a two-month extension of time, the fee for which can be charged to deposit account 02-2334.

Sincerely,



William P. Ramey, III
Reg. No. 44,295

Akzo Nobel Pharma Patent Department
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966
Tel: (302) 933-4034
Fax: (302) 934-4305